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NOTICE OF ALLOWANCE AND FEE(S) DUE

73230 7590 01/24/2012
DLA PIPER US LLP
2000 Avenue of the Stars
SUITE 400 North Tower
LOS ANGELES, CA 90067-4704

EXAMINER
CHANDRA, GYAN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/24/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,033	01/08/2008	Wei-Chiang Shen	374634-000078	5935

TITLE OF INVENTION: G-CSF TRANSFERRIN FUSION PROTEINS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$870	\$300	\$0	\$1170	04/24/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) have its own certificate of mailing or transmission. 73230 01/24/2012 Certificate of Mailing or Transmission DLA PIPER US LLP I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 2000 Avenue of the Stars SUITE 400 North Tower LOS ANGELES, CA 90067-4704 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 5935 10/575.033 01/08/2008 Wei-Chiang Shen 374634-000078 TITLE OF INVENTION: G-CSF TRANSFERRIN FUSION PROTEINS DATE DUE ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE APPLN, TYPE SMALL ENTITY YES \$870 \$300 \$0 \$1170 04/24/2012 nonprovisional **EXAMINER** ART UNIT CLASS-SUBCLASS CHANDRA, GYAN 514-001100 1646 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. ☐ Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and an apparation. Community is governed by 53 0.3.C. 122 and 57 CFR 1.14. Inis collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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73230 75	90 01/24/2012		EXAM	INER	
DLA PIPER US LLP			CHANDRA, GYAN		
2000 Avenue of the Stars					
SUITE 400 North Tower LOS ANGELES, CA 90067-4704			ART UNIT	PAPER NUMBER	
			1646		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

	Application No.	Applicant(s)		
	10/575,033	SHEN ET AL.		
Notice of Allowability	Examiner	Art Unit		
	GYAN CHANDRA	1646		
The MAILING DATE of this communication apperatus All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this appropriate communication GHTS. This application is subject to	olication. If not included will be mailed in due course. THIS		
1. This communication is responsive to <u>12/9/2011</u> .				
2. An election was made by the applicant in response to a rest requirement and election have been incorporated into this action.	riction requirement set forth during t	he interview on; the restriction		
3. A The allowed claim(s) is/are 1,8,9,11,14,15,19 and 25-28.				
4. ☐ Acknowledgment is made of a claim for foreign priority under a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" on the delow. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submit INFORMAL PATENT APPLICATION (PTO-152) which give 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must (a) ☐ including changes required by the Notice of Draftspers 1) ☐ hereto or 2) ☐ to Paper No./Mail Date	been received. been received in Application No cuments have been received in this of this communication to file a reply ENT of this application. ted. Note the attached EXAMINER's as reason(s) why the oath or declara t be submitted. con's Patent Drawing Review (PTO-	national stage application from the complying with the requirements S AMENDMENT or NOTICE OF tion is deficient.		
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.	s Amendment / Comment or in the C			
each sheet. Replacement sheet(s) should be labeled as such in the				
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.				
Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. ☐ Notice of Informal P 6. ☐ Interview Summary Paper No./Mail Dat 7. ☑ Examiner's Amendr 8. ☐ Examiner's Stateme 9. ☐ Other	(PTO-413), te		
/Gyan Chandra/				
Primary Examiner, Art Unit 1646				

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Lawrence McClure on 1/12/2012.

The application has been amended as follows:

Replace claim 11 with "The fusion polypeptide of claim 1, wherein the Tf domain is preloaded with two iron molecules."

In claim 14, line 2

Replace the term "the polypeptide of claim 1, 4, 5 or 9" with the term "the fusion polypeptide of claim 1 or 9"

Replace claim 19 with "A method of enhancing transport of G-CSF into or across a gastrointestinal (GI) epithelial cell, comprising contacting the GI epithelial cell with the fusion polypeptide of claim 1 under conditions that allow transport of the fusion polypeptide into the cell through TfR or transport of the fusion polypeptide across the cell through TfR via transcytosis."

Claims 12-13, 16-18, 20-24, 29 and 30 are cancelled.

Claims 1, 8, 9, 11, and 14-15 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 19 and 25-28, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, the restriction requirement between groups 1, 3 and 4 as set forth in the Office action mailed on 3/17/2009 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

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Art Unit: 1646

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/ Primary Examiner, Art Unit 1646